K023658

MAR 2 5 2003

510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

January 10, 2003

Carr Medical Products, Inc.
3735 N. Arlington Ave.
Indianapolis, IN 46218

Tel - (317) 542-0691
Fax - (317) 542-0694

Official Contact:	Alan L. Booker - Operations Manager
Proprietary or Trade Name:	Sterilization Cases, Trays, and Cassettes
Common/Usual Name:	Sterilization cases, trays, and cassettes
Classification Name:	Sterilization Wrapper Pack, Bag, and Accessories
Predicate Devices:	C/T Med-Systems Cassette system (Carr Medical Products) – K980065 Symmetry – PolyVac surgical instrument delivery system – K012105

Device Description:

Sterilization cases, trays, and cassettes designed to hold various general dental, medical device instrumentation during the cleaning, use, and sterilization process. The design is a container (case) with separate lid, which has various methods of holding the instruments in place. These are trays and cassettes, which are made of metal and plastic. They are available in various sizes ranging from [width x length x height (depth)] 10.375 " x 21.75" x 2.5" to 10.375" x 21.75" x 5" with trays and cassettes of similar size, which are stacked inside the case.

Indicated Use:

Medical device instrumentation cases, trays, and cassettes intended to hold instruments and accessories in place throughout the entire instrument use, cleaning, and sterilization cycle.

These cases, trays, and cassettes are suitable for Pulsing High Vacuum (pre-vac) steam sterilization at 132 ^{o}C for a 4-minute minimum with a 15-minute drying time.

Environment of Use:

Hospital, Operating Room (OR), physician and dental office or places where instruments are sterilized.

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Summary of Performance testing:

The Carr Metal Products Sterilization Cases, Trays, and Cassettes were independently tested according to AAMI TIR No. 12-1994 for their performance with the Pulsing High Vacuum (pre-vacuum) Steam sterilization method.

General Technical Characteristics

Attribute	Proposed devices
Indications for use	Indicated for holding medical device instrumentation in place throughout entire instrument use, cleaning, and sterilization cycle
Sterilization Method	Pulsing High Vacuum (pre-vacuum) steam sterilization at 132°C 4 minute minimum cycle with a 15-minute minimum drying time.
Intended to be reused	Yes
Intended Environment of Use	Hospital, Operating Room (OR), physician and dental office or places where instruments are sterilized
Design	
Various sizes of cases and lids and associated trays and cassettes offered	10.375 " x 21.75" x 2.5" to 10.375" x 21.75" x 5" with trays and cassettes of similar size, which are stacked inside the case
Utilizes various methods of holding instruments in place	Yes
May incorporate latch system to hold lid in place	Yes
Materials	
Aluminum, stainless steel, plastic	Yes
Performance Standards	
None under Section 514	Yes
Tested in accordance to AAMI TIR No. 12-1994	Yes
Validation study performed with half cycles to challenge sterilization method used	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates, C/T Med-Systems – K980065 other than larger sizes and Symmetry – PolyVac surgical instrument delivery system – K012105.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

Carr Metal Products, Incorporated
C/O Mr. Paul Dryden
ProMedic, Incorporated
6329 West Waterview Court
McCordsville, Indiana 46055-9501

Re: K023658
Trade/Device Name: Carr Sterilization Cases, Trays and Cassettes
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 10, 2003
Received: January 13, 2003

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K023658 (To be assigned)

Device Name: Carr sterilization cases, trays, and cassettes

Intended Use: Medical device instrumentation cases, trays, and cassettes intended to hold instruments and accessories in place throughout the entire instrument use, cleaning, and sterilization cycle.

These cases, trays, and cassettes are suitable for Pulsing High Vacuum (pre-vac) steam sterilization at 132 °C for a 4-minute minimum plus a minimum of 15 minutes drying time.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ **or** **Over-the-counter use** __
(Per CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023658